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An analysis of the proposed REACH regulation

Thomas Petry [a,*], Ruth Knowles [a], Richard Meads [b]

[a] THE WEINBERG GROUP LLC, 360, Boulevard du Souverain, B-1160 Brussels, Belgium
[b] Business Decisions Limited, Heronswood House, Maidstone Road, Pembury, Kent TN2 4DD, UK

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Abstract

In October 2003, the European Commission produced its first draft of its new chemicals legislation, known as REACH. At its core, REACH will require producers and users of chemical substances to register any use in a volume-triggered system. Mandatory submission of chemical assessment reports containing information on the hazards, exposures and risks associated with the uses of the chemical substances will be reviewed by government appointed expert committees. The marketing of substances considered to be of very high concern will require authorisation. This paper analyses issues related to the architecture of the proposed REACH regulation in light of its origins, drivers, its impacts on businesses and possible unintended consequences on other industries outside the chemical industry. Since the design of REACH reflects a range of different sources, goals and ideas, a number of its provisions are ambiguous in their current form. This creates uncertainty as to the implementation of the regulation. Regulatory certainty is, however, an essential pre-condition for the effective functioning of a modern market economy. As currently drafted, REACH could pose a challenge to the operation of the market economy in the EU.

Keywords: EU chemicals policy; EU chemicals legislation; Political drivers; Hazard versus risk; Workability; Legal certainty; Business impacts

1. Introduction

After the 2001 White Paper presentation on a Strategy for a Future Chemicals Policy (EC, 2001), the European Commission (EC) presented the first draft of a major revision of European chemicals management legislation at the end of October 2003 (EC, 2003a).

This proposal, known by the acronym "REACH" (Registration, Evaluation, and Authorisation of Chemicals), represents a major change in the way in which risks associated with chemicals will be managed in the European Union (EU). The proposed legislation will replace over 40 existing EU Directives and Regulations, ending the regulatory differentiation between new and existing substances as currently set out in the EU's Dangerous Substances Directive 67/548/EEC (EEC, 1967) and the Existing Substance Regulation, 793/93 (EEC, 1993).

The political review of the proposed REACH legislation is now in the co-decision process. This involves three of the European Institutions; the European Commission (EC), the Council and the European Parliament (EP). These institutions all have different roles within varying stages of the process. The process is illustrated in a simplified form in Fig. 1. A regulatory proposal is adopted when the Council and the European Parliament agree on a proposal prepared by the Commission. REACH will be implemented once published in the Official Journal of the European Communities. The Commission expects this to happen in late 2006 or early 2007.

This paper seeks to summarise and review the fundamental architecture and the origins and drivers of the proposed REACH regulation, analysing some key issues related to the design of REACH and its impacts on businesses. A particular focus is given to issues that threaten the

* Corresponding author. Fax: +32 2 626 11 79.
E-mail address: thomas.petry@weinberggroup.com (T. Petry).

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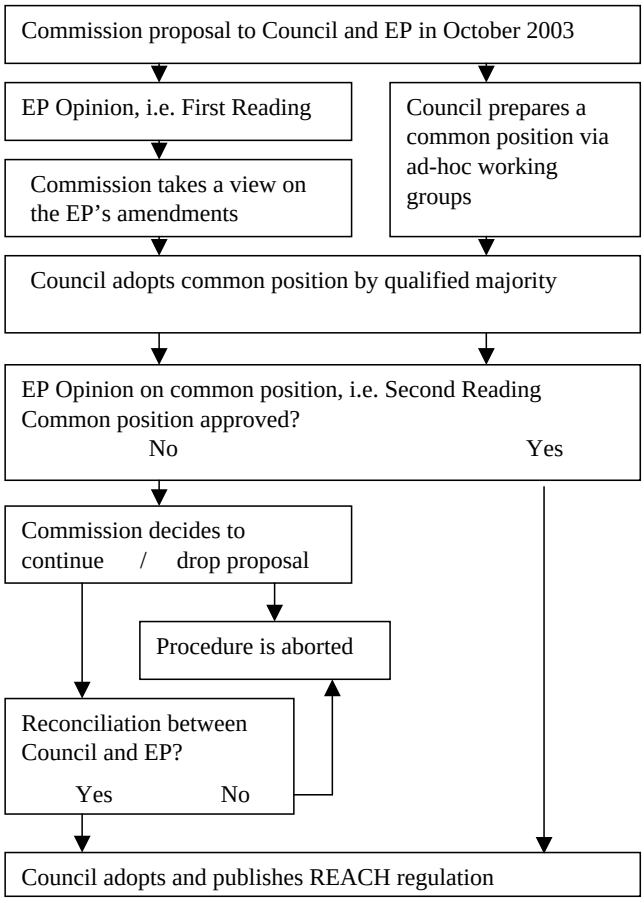

Fig. 1. The Co-decision procedure.

workability of REACH and the competitiveness of European industry.

2. The architecture of REACH

REACH will pull approximately 30,000 chemicals into its registration, evaluation, authorisation and restrictions provisions. A European Chemicals Agency will be created to manage the technical, scientific and administrative aspects of the REACH system at a Community level. The four major elements of reach; Registration; Evaluation; Authorisation; and Restriction, covered in detail in the published proposal (EC, 2003a), are described briefly below.

2.1. Registration

Manufacturers and importers will be required to gather information on the properties of their substances and to submit the information in form of a registration dossier to a central database, managed by the European Chemicals Agency. In order to manufacture a substance or import it into the European market at volumes of 1 tonne or more per year, companies will be required to register all uses of chemical substances, either used on their own or in preparations. Companies must provide information on the intrinsic properties and hazards of each substance and the use(s) of the substance as identified by the importer or manufacturer or by their customers in the form of a Chemical Safety Report for volumes of more than 10 tonnes per year. The information given to the European Chemicals Agency by manufacturers and importers undergoes an *Evaluation* process by competent authorities in Member States.

2.2. Evaluation

There are two types of evaluation: dossier evaluation (to determine the compliance of the registration with registration requirements and whether sufficient test data are already available to evaluate a substance) and substance evaluation (performed whenever a Member State or the Agency believes that there are reasons for suspecting that uses of a substance may represent a risk to human health or the environment). The Agency's role will be to develop guidance on prioritisation of substances for evaluation. The Member States then prepare rolling plans of the substances that they wish to evaluate. Substances with a certain hazard profile that are considered to be "of very high concern" will be made subject to a mandatory *Authorisation* process.

2.3. Authorisation

In this stage, the Commission is responsible for granting or refusing authorisations to manufacture, import or use chemical substances. Substances that will be subject to authorisation are

- Category 1 or 2 CMRs (carcinogenic, mutagenic or toxic to reproduction);
- PBTs (persistent, bio-accumulative, and toxic);
- vPvB (very persistent, very bio-accumulative); or
- Substances identified as having serious and irreversible effects to humans and the environment equivalent to the other three categories. Identified on a "case-by-case" basis.

Applicants will have to demonstrate that the risks associated with their substances are adequately controlled, if authorisation is to be granted. Alternatively an authorisation may be granted for uses of substances if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies.

The authorisation mechanism also contains provisions that enable risk-reduction measures to be introduced across the EU when the risks are found to be "unacceptable." This is the *Restrictions* element of REACH.

2.4. Restrictions

The European Commission considers restrictions to be the "safety net" of the system. Restricted substances cannot be manufactured, placed on the market, or used unless they comply with the conditions of the restrictions. Proposals

for restrictions must be prepared by the Member States or the Commission in the form of a structured dossier.

3. The origins and drivers of REACH

EU regulations to control risks from industrial chemicals were first drafted in the 1960s and 1970s to facilitate trade in the common market. Since the early and mid-1980s, environmental and health issues have become increasingly important to EU policy-makers; stimulating alterations and amendments of the original legislation. An example of this is the Dangerous Substances Directive 67/548/EEC (EEC, 1967), which, since its adoption in 1967, has been amended nine times and adapted a further thirty times to reflect technical progress. Despite these changes, however, EU institutions see the Directive as confusing and lacking satisfactory levels of health and environmental protection.

The design of REACH has also been influenced by the EU's evolving legal framework for risk management, especially the precautionary principle. The treaty of the European Union requires policy makers to make use of the precautionary principle to protect the environment. In 2000, the process for applying this was set out by the Commission (EC, 2000). This defined the principle as a risk management tool to be used in a limited set of circumstances. However, recent judgements on the decisions by the European Court of Justice (ECJ) have expanded the scope of the principle to include human health. Such judgements reduced the need for officials to have scientific evidence of hazard before the precautionary principle may be applied[1].

Pressure for change has also come from outside the EU. For example, the outcomes of the United Nations Conference on Environment and Development (UNCED) in Rio in 1992 (UNCED, 1992), and the adoption of the generation goal in the OSPAR and HELCOM conventions (HELCOM, 1998; OSPAR, 1998), made it increasingly clear that the existing legal instruments used for chemicals management in the EU needed to be reviewed. In response, the European Council of Ministers and the Commission declared that an integrated policy with the main objective to protect human health and the environment was needed. Such a policy was supposed to embrace the precautionary and sustainability principles, and make major contributions to achieving the objectives defined in the above conventions.

The drive by a number of OECD countries to pursue new policy initiatives to improve the management of chemicals reflects regulatory failures (such as BSE), declining levels of public trust in government institutions, and rising concerns amongst activists and the media about exposure of citizens to "involuntary" risks from chemicals (Lofstedt, 2004). More importantly, a significant number of citizens in many OECD countries have become more risk averse and, increasingly look to government action for protection against risks of all types (Moss, 2002).

From 1998 to 2001, the Council and Commission drafted a new chemicals regulation in consultation with other stakeholders. Industry reacted by highlighting the launch of voluntary programmes. In 2001, the European Commission finally adopted its "White Paper on a Strategy for a future Chemicals Policy" and in 2003, the Commission presented its first draft of the new chemicals legislation.

4. Some issues and concerns with REACH

In its design, REACH can be seen as a compromise between distinct and different groups of ideas about the best way to manage toxicological risks. Because the design of REACH reflects such a range of different sources, goals, and ideas, many of its provisions are ambiguously drafted. This tends to permit differing interpretations and thus different approaches to implementation.

In the course of developing REACH, the European Commission actively engaged with the various stakeholders by setting up technical working groups, exchanging and discussing views in workshops and conferences and finally by launching an Internet consultation to review the workability and technical requirements of a 'pre-draft' of the legislation, published in April 2003 (EC, 2003b).

In its Explanatory Memorandum, the Commission stated that the internet consultation alone generated more than 6000 distinct contributions from stakeholders. The main concerns that were raised, and that the Commission claimed to have addressed in its proposal from 29 October 2003, were related to the scope of the REACH system, legal certainty, costs, bureaucracy, and confidentiality of information, substitution, animal testing; and benefits and impacts of the proposed scheme.

Although substantial improvements were made to the pre-draft of the legislation, a range of issues raised by stakeholders in the design of the regulation, which could significantly affect the workability and the costs of the regulation, were not significantly addressed . An overview of the issues raised are presented in Fig. 2. In summary these are: "

- The scope of REACH is still too wide;
- REACH represents a system that prioritizes the review of chemical substances and encourages substitution of chemical substances based on intrinsic hazardous properties and not the risk their posing to human health and the environment;
- Ambiguous language and unclear or inadequate criteria leading to uncertainty;
- Uncertainty relative to the consideration of risk or risk-benefit in the authorisation and restriction review;
- Costs and benefits of the regulatory regime and
- Unintended consequences for materials traditionally not managed within the context of chemicals legislation.

[1] European Court of First Instance, Case T-13/99 Pfizer Animal Health S.A. v. Council, 2002; European Court of First Instance, Case T-70/99, Alpharma v. Council, 2002.

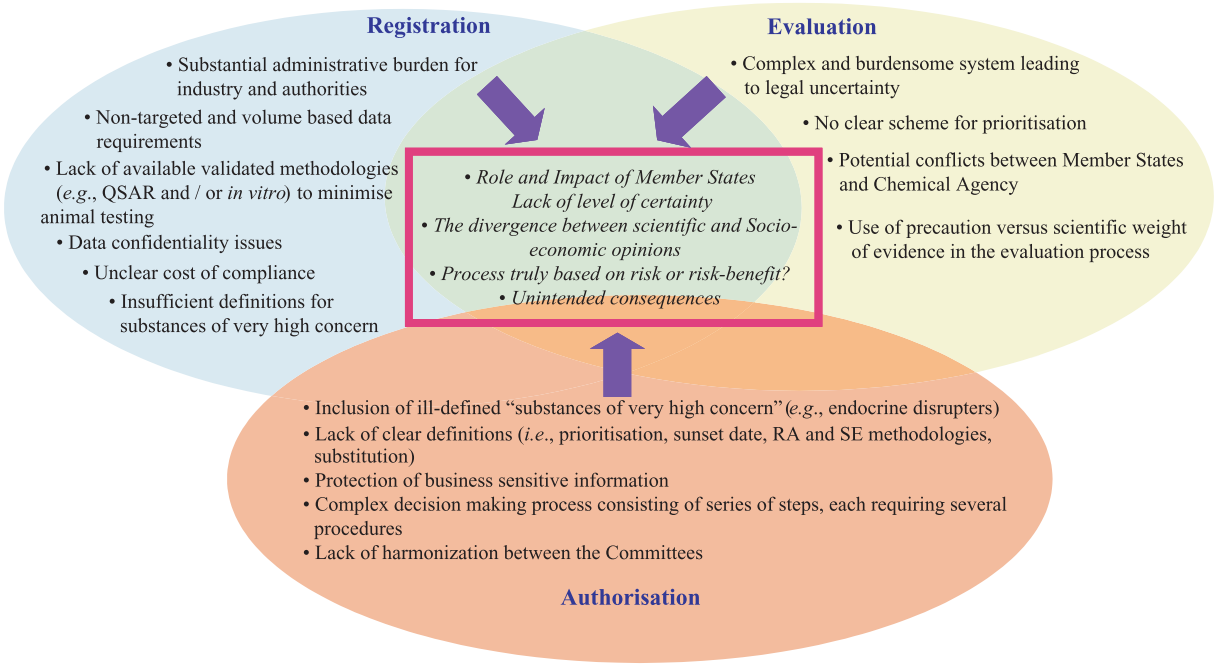

Fig. 2. Articulated issues and concerns with REACH.

The scope of REACH has been considered by many stakeholders as still too wide and burdensome, potentially threatening the workability of the system. Unintended consequences of REACH on various 'materials' industries may arise from the fact that REACH has been originally designed for organic chemicals and are not directly applicable to the circumstances of inorganic sectors such as the ceramics, minerals, metals or glass industry. There a number of examples where the scope of REACH could be limited without compromising on the protection of human health and the environment, one of the key objectives of the proposed REACH legislation.

For example, the inclusion of minerals, ores or other substances occurring in nature that are classified as dangerous according to Directive 67/548/EEC largely increases the number of substances that have to be registered under REACH. The Metals Forum, an alliance of the metals and alloys industry, has estimated that this provision will result in several hundred additional registrations for many thousands of uses, to be made by the metals industry alone, and thereby more than double the total number of registrations for this sector. The potential risks arising from the use of these raw materials are already regulated and covered under the IPPC Directive 96/61/EC and other workplace regulations such as the Chemicals Agent Directive 98/24/EC and the Carcinogens Directive 2004/37/EC. Hence, it appears questionable if the consideration of minerals and ores under REACH will lead to any benefit for human health or the environment. Any risks associated with the downstream uses of the constituent materials of minerals or ores will be covered in the respective metal registration dossiers (Metals Forum, 2003).

Another important issue that will significantly impact the workability of REACH are the requirements on substances in articles. In particular Article 6(2), which foresees the requirement to notify substances that are likely to be released under normal and reasonably foreseeable conditions of use in quantities that 'may adversely affect human health and the environment,' even though this release is not an intended function of the article, imposes significant data collection, chemical analysis and paperwork.

There are a huge number of articles on the European market. The thresholds and terminology contained in Article 6(2) are unclear and the legislation does not provide any guidance or methodologies for manufactures to establish their obligations under this provision. As it stands today it will be at the discretion of the competent authorities to how these provisions will be applied once implemented: no standards or thresholds are provided. Furthermore, it is unclear as to what additional benefits to human health and the environment are likely to be achieved. Under the General Product Safety Directive 2001/95/EC (EC, 2002), manufacturers of articles are already obliged to market only products that are safe.

Through the comitology process, there is the risk that EU decisions on management of risk can be politicised. Under this, scientific and other risk assessment advisers make recommendations to committees composed of Member State representatives. Formal decision-making powers reside with these committees. Research amongst high-tech companies suggests that such a political process has the potential to reduce regulatory certainty (Business Decisions Limited, 1997; Business Decisions Limited, 2002). REACH, as currently drafted, has the potential to increase regulatory uncertainty in the EU.

Regulatory certainty is, however, an essential pre-condition for the effective functioning of a modern market econ-

omy. Without it, incentives for investment are undermined, new product development is curtailed, and existing products are removed from markets. A number of key provisions of REACH fail to provide certainty for businesses, not only for their investment and growth, but also for their knowledge of compliance requirements. In addition to the issues related to the provisions of substances in articles discussed in the previous paragraph, the issue of failure to provide certainty applies also to some of the criteria triggering authorisation for chemical substances and the actual authorisation review process.

For example, the proposed Article 54(f) stipulates the requirement to include substances which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed in paragraphs (a)–(e) of Article 54 (i.e., substances considered to be Category 1 or 2 carcinogens, mutagens, or reproductive toxicants according to Directive 67/548/EEC; persistent, bioaccumulative and toxic; or very persistent and very bioaccumulative) on a case by case basis into the list of substances subject to authorisation of the regulation (i.e., Annex XIII). In this context, substances with endocrine disrupting properties are mentioned as a case that could trigger this provision.

Article 54(f) lacks certainty, because it specifically eliminates the criteria established in 54(a)–(d) in favour of a non-scientific vague standard of "equivalency." This criterion, which is applied on a "case-by-case" basis, is highly subjective and effectively introduces a "catch-all" provision, allowing to bring in substances targeted for political reasons into the most highly regulated category. Nor does the reference to endocrine disrupting substances establish criteria that can be properly applied. There is no definition of endocrine disrupting substances in EU legislation. Moreover, there is no agreement yet among scientists on the definition or on the testing methodology to identify an endocrine disrupter (WHO, 2002).

The well intentioned REACH regulation is hampered by its ambiguous legal drafting, the reliance on guidelines, and the increase in administrative discretion. Limited rights or procedures for appeal of agency conclusions, create uncertainty for those implicated. The absence of a risk standard and how it will be defined and implemented are the most important issues. REACH does not define the levels or characteristics of risk that may trigger regulatory actions quantitatively. In context of the authorisation procedure, REACH requires consideration of the socio-economic importance of a chemical and its uses, and the appropriate levels of controls that reduce risks, but provides little specification. It is unclear how and on what basis substitution will find considerations in the final decisions. In Recital (7) of the proposal, the Commission stressed the objective to substitute substances considered to be dangerous by less dangerous substances, completely ignoring the risks that are being posed by such 'dangerous' substances.

Experiences from current legislation with similar processes, such as the review of classification and labelling under the dangerous substance directive 67/548/EEC (EEC, 1967) and existing substances regulation 793/93 (EEC, 1993), fuel the suspicion that for substances with complex toxicological profiles, recommendations of the competent authorities will be of a precautionary nature and not always be based on the scientific weight of the evidence. The requirement of existing legislation, to consider the human relevance of animal toxicity data, may well be ignored. These concerns were already recognised by the European Commission. In a joint letter by DG Enterprise and DG Environment to the Working Groups (WG) on Classification and Labelling, which is composed of representatives from the Member States, the Commission reminded the WG that their recommendations have to be based on solid science, using a weight-of-evidence approach and considering the conditions of normal handling and use of chemical substances (ECB, 2003). The European Commission also stressed to the WG that it has no political mandate.

As the evaluation process within REACH is similarly constructed to that of the review of classification and labelling, there is concern among industry that the scientific review process under REACH will lack harmonization. Although the Commission has already strengthened the responsibility and power of the Agency, the role of Member States in the outcome of the evaluation process is still significant. It appears that the only way of solving this issue is to make the Agency solely responsible for the whole REACH process.

5. Business impacts of REACH

A critical discussion of the proposed REACH regulation would be incomplete without an examination of the benefits and costs of REACH for business. There is probably no other issue in context of REACH that has been more controversially discussed than the impacts of the proposed REACH legislation on industry and society as a whole.

The following review aims at highlighting and discussing some of the issues that should find consideration in the assessment of the business impacts of proposed REACH regulation. It will focus on the benefits and costs of REACH for businesses from a competitiveness point of view. The review does not attempt to analyse the benefits of REACH for society and businesses from a human and environmental protection standpoint nor does it look at the methodology of modern regulatory impact assessment and the quantitative outcomes of the businesses impact assessments conducted on REACH. These topics have been discussed elsewhere (ECORYS and Opdenkamp Adviesgroep, 2004; Kramer et al., 2004).

5.1. Benefits of REACH

The supporters of REACH in its current form stated that REACH will enhance the competitiveness of producers and users of chemicals in the EU for the following reasons (World Wildlife Fund and the European Environmental Bureau, 2003)

- Restrictions on the use of dangerous materials and the increased awareness amongst citizens of the importance will create new markets for safer products. New market opportunities may offset the economic losses identified by businesses.
- Conditions for investment in production and development of chemicals will be improved in the EU because of increased public trust and consumer confidence. Greater availability of information about the intrinsic properties and uses of existing chemicals and a rigorous evaluation of this information by governments will allay fears of hidden dangers.
- EU producers of new, safer materials will have "first mover" advantage in export markets because of an emerging harmonisation of safety standards. This presumes that REACH will become the new standard for chemicals management globally, leading to benefits for EU businesses that have taken steps to innovate in response to regulatory pressures.
- New market opportunities for innovative development of new product and service packages will be created because of better relationships between suppliers and users. REACH will expand the understanding that producers have of the uses and users of their substances. Increased knowledge should provide opportunities for innovation based a more comprehensive knowledge of customer needs.
- Increased innovation by EU producers and importers will take place as a result of reduced testing requirements for some new substances and a more coherent legislative environment. For certain types of new product, the REACH system will require fewer tests than the existing pre-market approval process.

On the first spot these arguments are plausible, but require further considerations: the assertion that substitutes will emerge if restrictions are placed on the use of existing materials is questionable in a free market. In free economies, market needs are only met if this can be achieved profitably. If there is no market for new 'safer' products because customers place little value on this, the cost of product development cannot be met by new revenues, or if better opportunities exist for resources outside the EU, then the need will no longer be met. Experiences from the veterinary medicines sector illustrate this (Business Decisions Limited, 1997; Business Decisions Limited, 2002). It illustrates how well-intended EU regulation to manage hazards posed by chemical substances used in animal drugs resulted in large-scale withdrawals of existing products despite the presence of clearly defined needs. The overall result was a veterinary medicines availability crisis for niche products with low volumes and reductions in food safety and animal welfare.

Similar observations were made following the implementation of the pesticide directive 91/414/EEC (EEC, 1993) where it has been estimated that only about 30% of existing pesticides will be re-registered. It has further been estimated that about 70% of the R&D budgets for Agrochemicals were spent on registration/re-registration as opposed to developing new innovative products (CEFIC, 2004). Hence, in an environment of declining markets for agrochemicals (largely because of the effectiveness of existing agrochemicals), an insufficient amount of money was available for innovation and development of 'safer' pesticides.

It is further unclear as to whether REACH will increase consumer confidence. REACH is a long-term strategy to manage chemicals. Over a period of at least eleven years, uses of substances will be registered, evaluated, and authorised. This process will generate innumerable risk management decisions many of which will be contested, and some of which will be controversial. In an emotional environment of claim and counter-claim about safety, it is difficult to imagine how overall confidence in chemicals will be increased. Without market confidence, businesses are unlikely to invest in new products or processes.

The assertion of potential "first mover" advantages in global markets is based principally on research carried out into the impact of pollution control standards on markets for process equipment (Porter, 1990; Porter and van der Linde, 1995). It reflects the assumption, that REACH will become the "gold standard" for consumer and environmental protection, and will be copied elsewhere. Attaining these prospective gains depends on the EU being able to 'export' its approach to the management of chemical safety. In particular, the EU needs to convince other OECD countries and the emerging major markets in Asia. The majority of OECD countries appear to be pursuing policies based on risks, rather than hazard, precaution and substitution as the underlying principles. Countries such as China, in contrast, appear to be more concerned to manage the direct damage caused by industrial activity than to establish new all-encompassing controls over chemicals and their uses at all parts of the industrial value chain. The comments of WTO Member Countries on the REACH proposal in context of a WTO TBT meeting support this view.

It is possible, therefore, that products developed to comply with REACH may, in fact, end up trapped in the EU market, with only few, if any additional competitive benefits. This problem could be worsened if non-EU producers are able to make use of chemical and materials technologies embedded in substances of "very high concern": under REACH use of these will require authorisation in the EU, a hurdle that is likely to limit innovation based on such substances by EU producers.

Finally and probably most importantly, there is the problem of regulatory uncertainty. The scale of REACH, its design, and its processes will likely increase rather than reduce administrative discretion in the EU. This will make it more difficult for businesses to predict regulatory outcomes. For companies this has the effect of reducing the attractiveness of retaining existing products or developing new ones in the EU.

5.2. Costs of REACH for business

As with the benefits of REACH, there is no consensus as to its costs. The supporters of REACH predict that the

costs of REACH will be limited to a small increase in the price of chemical products. This will, however, have no other material impact on the EU's economy. Over time, any small economic costs will be outweighed by the economic benefits. Under this model, the limited costs of greater environmental and social protection are paid for by citizens through marginal increases in the price of everyday goods (World Wildlife Fund and the European Environmental Bureau, 2003).

Initial formal assessments by the Commission tend to support this view, although its findings and methodology have been heavily criticised by business organisations and some Member State governments (EC, 2003c). Most notably, the critics point to a failure to consider the possibility of global trade (the Commission's model assumed a closed EU economy), and to consider fully dynamic or indirect responses by businesses to regulatory costs. It is further believed that the Commission did not appropriately consider the processes by which businesses decide whether or not to retain products that face new, mandatory safety tests. The Commission's findings tend to be based on relationship between sales revenues and testing costs, whereas critics believe, that such decisions are based on calculations of the relationship between additional costs and available margin (ie., revenues minus avoidable costs for the remaining years of the product's life) (Brealey and Myers Principles of Corporate Finance, 1988).

Through a series of extended impact assessments, business organisations claim that REACH is likely to impose substantial economic costs on companies (Little, 2004; Mercer Management Consulting, 2003). Two types of costs have been identified by these studies: direct and indirect costs.

Business organisations stated that there are likely to be high levels of "initial" or direct impacts such as higher testing costs, and the increased costs, time, and uncertainty associated with obtaining authorisation of uses of substances of very high concern. Other possible direct costs identified by businesses include potential barriers to innovation and efficiency if producers remove existing substances from the market, and the possible loss of resources for innovation if new safety tests are required for existing substances ("defensive R&D").

As well as these problems, industry claims that there will also be dynamic or indirect costs as companies respond to regulatory change. It is these responses that will determine the overall, negative impact of REACH. Predicting these responses is, as is acknowledged by all stakeholders, extremely difficult. Business organisations, particularly in France and Germany, commissioned major studies from leading independent consultants (Little, 2004; Mercer Management Consulting, 2003). Using a bottom–up approach based on extensive interviews with company managers, these attempt to predict how companies in different sectors might respond to the 'direct' impacts of REACH.

This method has, however, been criticised by NGOs and partly the Commission. Their view is that businesses are not a suitable or reliable source of information in this situation, and that other tools and sources should be used to estimate how businesses might respond to regulatory change (ECORYS and Opdenkamp Adviesgroep, 2004).

In response, supporters of the methodology used by Mercer and Little stated that decisions as to how businesses respond to regulatory changes are made by managers and investors. Views of managers are, therefore, the most important source of information about possible business responses to regulatory change. The challenge for researchers is to find ways to identify these views that recognise the potential for over-estimation. Moreover, modern research into determinants of productivity in economies (an analogous problem for researchers) focuses increasingly on using bottom–up, company-based methods rather than traditional top–down economy-wide models.

On the basis of these and other studies, business organisations believe that REACH could trigger a range of different responses by companies. They include reductions in the number of substances available for downstream users, diverting R&D away from innovation, increases in prices for consumers, and reductions in output and employment.

Extensive substitution of 'dangerous' substances for safer alternatives by downstream users could lead to revenue losses for producers, and reductions in output and employment in sectors affected by changes in usage patterns; reduced efficiency and profitability of EU investments, leading to loss of market share in the EU and export markets, and 'delocalisation' as businesses switch production away from the EU, so as to maintain the competitiveness of final articles; and reduced investment in production facilities and product development in the EU by global businesses because of increased political risk due to regulatory uncertainty in the EU.

There are obvious problems with the claims made by business organisations. Response is likely, for example, to differ by sector and the certainty of response is hard to estimate. Competitive problems facing businesses in short life-cycle sectors, such as consumer electronics, are very different from those facing businesses in capital goods industries. Research suggests that regulatory change is most likely to induce the greatest change in business behaviour if it affects the capacity of companies to compete or threatens their ability to survive (or meet the basic needs of investors) (OECD, 1997a,b; UNICE, 1995). In other words there is no simple, deterministic process at work and any relationship between regulatory change and business response is extremely hard to quantify.

Despite these problems, research carried out in sectors that have already experienced REACH-type regulatory changes (e.g., the animal health and pesticide sector) shows how companies respond to the imposition of new safety testing requirements on existing products, and to regulatory uncertainty in market approval processes. This evidence highlights how companies reduce the availability of existing products, and shift R&D priorities away from certain types of technologies and markets. More importantly,

the research shows how, in response to lower revenues (because of fewer products) and fewer product development resources (due to defensive R&D), companies shift assets away from the EU. (Business Decisions Limited, 1997; Business Decisions Limited, 2002; CEFIC, 2004).

We have so far largely focused on the economic costs of the REACH proposal. However, there may also be social costs which, unlike the economic costs, will be much harder to quantify (Durodie, 2003). Durodie argues that the public's "right to know" mentioned in the White paper, may reduce the inventiveness of society and undermine society' confidence in science and scientific decision making. Not only this, but efforts to increase regulatory stability by taking on board public views and values into the decision making process may "… prove to be very short-sighted, as policy determined from opinion is likely to prove far more unpredictable than that based on evidence." (Durodie, 2003).

6. Conclusions

All stakeholders support the broad objectives of REACH. Even its most strident critics recognise that new measures are needed to manage chemicals risks in the face of the lack of safety information on a number of widely used chemicals and the increased risk aversion amongst the EU's citizens.

But the different stakeholders cannot agree on the proposed content and design of the REACH system. Our review tends, in general, to endorse many of the criticisms that are made of the proposed regulation. The provisions are often unclear and ambiguous, and, probably, unworkable in its current form. In view of its scope, the impact of these flaws will be experienced by most manufacturing businesses in the EU.

Yet deep within it, REACH poses another risk. As currently proposed, it could provide the basis for central planning of technology use throughout the EU's manufacturing sector. Through a combination of the nature of the proposed authorisation and evaluation processes, the focus on case-by-case substitution, and well-intended attempts to ensure that all exposures to substances are brought within the scope of the legislation, REACH could pose a challenge to the operation of the market economy in the EU. Under REACH, officials, rather than markets, have the potential to make decisions about which materials companies can use in hundreds of thousands of applications in every manufacturing sector.

As REACH is now going through the political review process, there is a great opportunity to address some of the issues identified in this paper and also by others. More focus and clarity is needed. REACH is a very important legislation which will basically impact all industry sectors, not only the chemicals sector. It is therefore very important to get it right, from both a human health and environmental point of view and from a competitiveness point of view.

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